

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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DR. ROBERT V. VITOLO,

Plaintiff,

**MEMORANDUM
AND ORDER**

-against-

98CV2837(SLT)(VVP)

MENTOR H/S, INC.,

Defendant.

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TOWNES, U.S.D.J.

In this diversity action, Plaintiff seeks damages for losses sustained in removing and replacing certain saline breast implants from patients who suffered complications therewith. Plaintiff alleges that he was fraudulently induced to enter an agreement with the manufacturer, Defendant Mentor H/S, Inc., and was intentionally misled as to the safety of the implants, causing him monetary damages as well as damages to his professional reputation. Though the Complaint alleges causes of action sounding in negligence and breach of contract, those claims were dismissed pursuant to stipulations on June 4, 2002, and March 8, 2006, respectively. Defendant seeks summary judgment dismissing the remaining claims of fraud, fraudulent inducement to enter a contract, and a violation of New York's General Business Law § 349. Based upon all submissions of the parties and oral argument held on March 17, 2006, and for the reasons stated below, Defendant's motion is granted in full.

FACTS AND PROCEDURAL HISTORY

Plaintiff Robert V. Vitolo, M.D. (“Plaintiff” or “Vitolo”) is a plastic surgeon with several offices in the New York City metropolitan area. (Def. 56.1 Stat. ¶ 1.) Defendant Mentor H/S, Inc., (“Defendant” or “Mentor”) is a subsidiary of Mentor Corporation, and manufactures, *inter alia*, saline-filled breast implants. (Def. 56.1 Stat. ¶ 2.) From approximately the early 1980s until August 1995, Defendant sold saline-filled implants known as the “1800 Series Smooth Round Marry Implant with Leaf Valve” (hereinafter “MLV”). (Def. 56.1 Stat. ¶ 3.) Though Plaintiff originally obtained his implants from McGhan Medical Corp. (“McGhan”), by late 1994, Plaintiff’s business became extremely successful and his demand for implants began to exceed McGhan’s ability to supply them. In response to Plaintiff’s inquiry, Michael Lawrence, a Mentor sales representative, came to New York to discuss Mentor’s implants with Vitolo. (Def. 56.1 Stat. ¶¶ 13-14.)

During their meeting, Plaintiff specifically requested the MLV implant. (Def. 56.1 Stat. ¶15.) At the time, Plaintiff had begun performing breast augmentation surgery using the umbilicus technique, in which, to reduce scarring, the implant would be inserted through the patient’s navel, Def. 56.1 Stat. ¶¶ 10-12, as opposed to prior techniques that involved insertion in the armpit or along the breast. (Def. 56.1 Stat. ¶ 6.) Defendant claims that Plaintiff was cautioned against use of the umbilicus technique with the MLV. (Def. 56.1 Stat. ¶¶ 8-11.) Defendant warned that the device “may be easily damaged by surgical instruments or ruptured by excessive stresses, manipulation with a blunt instrument or penetration by a needle.” (Def. 56.1 Stat. ¶ 9.) Though Defendant argues that, “[b]ecause the umbilicus procedure involved the use of a surgical instrument to move the implant from the belly button to the breast, the use of

this procedure was inconsistent with [its] recommendations,” Def. 56.1 Stat. ¶ 10, Plaintiff argues that all methods of implantation involve contact between the implant and surgical instruments, and that Defendant’s warning therefore did not serve as a warning specifically against the umbilicus technique. (Pl. 56.1 Stat. ¶ 10.) Furthermore, Plaintiff argues that Defendant knew of and condoned the umbilicus procedure and recruited him knowing that it was his procedure of choice. (Pl. Mem. of Law Ex 36 (Vitolo Aff.) ¶ 7.)

The parties entered into an agreement whereby Defendant supplied Plaintiff with MLV implants. After Vitolo’s patients experienced a total of 19 deflations within four months, Defendant exchanged the MLV implants for the Mentor 1600 Series Diaphragm Valve implants and began investigating the “unusually high” number of deflations that Plaintiff’s patients suffered. (Def. 56.1 Stat. ¶¶ 19-21.) Pat Altavilla, Mentor’s Executive Vice President of Marketing (“Altavilla”) hypothesized that the umbilicus procedure was related to the number of deflations. (Def. 56.1 Stat. ¶ 24.) Plaintiff disputes this allegation, pointing out Defendant’s failure to perform any scientific studies or analyses in support of this hypothesis. (Pl. 56.1 Stat. ¶ 24.)

Thereafter, in mid-1995, Altavilla traveled to New York to observe Plaintiff performing the umbilicus procedure. (Def. 56.1 Stat. ¶ 26.) The night before the surgery, Plaintiff and Altavilla went to dinner at a restaurant. Unbeknownst to Altavilla, Plaintiff was tape recording their conversation. (Def. 56.1 Stat. ¶ 26.) During the dinner conversation, Plaintiff was adamant that the umbilicus procedure was not responsible for the high number of deflations. (Ex 7 to Def. 56.1 Stat. at 39-43.) Altavilla encouraged Plaintiff to go to Dallas, Texas, to reproduce the surgery for the benefit of Defendant’s engineers, who would presumably study and determine

the cause of the deflations. (*Id.* at 44-46.) Plaintiff never went, explaining that “that’s what [Altavilla] offered but it never came to pass. It’s just like me inviting you to dinner to be polite but you never get taken out to dinner.” (Pl. 56.1 Stat. ¶ 33.)

The MLV came with a product replacement policy, providing that Defendant would provide a free replacement device and up to \$1,000 in reimbursement for hospital and anesthesia fees. (Def. 56.1 Stat. ¶ 16.) Plaintiff argues that the offer for reimbursement was illusory, as it was conditioned upon patients signing a general release absolving Mentor for any tort liability, which patients were predictably reluctant to do. (Pl. 56.1 Stat. ¶ 16.) Nevertheless, after Plaintiff read a magazine article denouncing the umbilicus technique, he asked Altavilla to prepare a letter informing patients that Defendant would continue to honor its product replacement policy for patients who elected implantation using the umbilicus technique. (Def. 56.1 Stat. ¶¶ 34-5.) By this time, Plaintiff no longer used the MLV implant in new surgeries, though prior patients continued to complain of deflations thereof. (Def. 56.1 Stat. ¶¶ 36-7.)

Defendant conducted an investigation of the MLV implants, and discovered, *inter alia*, that an increased rate of deflation occurred when the implants were “autoclaved” (steam sterilized prior to implantation). Defendant issued a “Dear Doctor” letter on September 1, 1995, in which physicians were advised of the dangers of autoclaving, as well as Defendant’s finding that deflation could also occur when the MLV was implanted with the umbilicus procedure. (Def. 56.1 Stat. ¶¶ 46-47.) Plaintiff argues that the “Dear Doctor” letter is misleading, in that autoclaving a sterile implant prior to implantation is a rare event. (Pl. 56.1 Stat. ¶ 46.) Plaintiff alleges that Defendant knew the implants were defective but feared a public relations nightmare. (Pl. Mem. of Law Ex. 20.) As a result, Plaintiff argues, Defendant sent a copy of the “Dear

Doctor” letter to the Food and Drug Administration (“FDA”), prompting a Class II recall (which does not require manufacturers to physically recall the product). (Def. 56.1 Stat. ¶ 48.) Despite the fact that this was not the type of recall that required Defendant to take the product off of the market altogether, Defendant nevertheless discontinued the MLV and destroyed its entire inventory. (Def. 56.1 Stat. ¶ 50.)

Plaintiff alleges that Defendant misrepresented the failure rate, inducing him to purchase the MLV implants. Plaintiff argues that Defendant knew the product contained defective valves, which, Plaintiff implicitly argues, is why Defendant destroyed \$2 million worth of implants following the recall. (Pl. 56.1 Stat. ¶¶ 51-53.) Plaintiff filed the instant complaint (the “Complaint”) in the Supreme Court of Richmond County on February 11, 1998, stating causes of action for negligence, breach of contract, fraud and fraudulent misrepresentation, and a violation of New York’s General Business Law § 349 and on April 14, 1998, Defendant filed a Notice of Removal. On June 4, 2002 and March 8, 2006, the parties signed stipulations dismissing Plaintiff’s negligence and breach of contract claims, respectively. What remains are Plaintiff’s claims of fraud and fraudulent inducement and Plaintiff’s claim under New York’s General Business Law § 349, and Defendant seeks summary judgment on each of those claims.

DISCUSSION

Summary judgment is appropriate where “there is no genuine issue as to any material fact.” Fed. R. Civ. P. 56(c). “A fact is ‘material’ for these purposes if it ‘might affect the outcome of the suit under the governing law.” *Holtz v. Rockefeller & Co.*, 258 F.3d 62, 69 (2d Cir. 2001) (*quoting Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986)). To be “genuine,” an

issue of fact must be supported by evidence “such that a reasonable jury could return a verdict for the nonmoving party.” *Holtz*, 258 F.3d at 62. Because the moving party bears the burden of showing that there are no genuine issues of material fact, *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986), “a court must resolve all ambiguities and draw all reasonable inferences against [it].” *Alston v. New York City Transit Authority*, 2003 U.S. Dist. LEXIS 21741, *4 (S.D.N.Y. 2003) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986)).

A. *Section 349 of New York’s General Business Law*

“Section 349 of the General Business Law was intended to be a consumer protection statute.” *Teller v. Bill Hayes, Ltd.*, 213 A.D.2d 141, 145 (N.Y. App. Div. 1995). “In fact, prior to 1980, only the Attorney General could prosecute an action pursuant to General Business Law § 349.” *Id.* “The typical violation contemplated by the statute involves an individual consumer who falls victim to misrepresentations made by a seller of consumer goods usually by way of false and misleading advertising.” *Genesco Entertainment v. Koch*, 593 F. Supp. 2d 743, 751 (S.D.N.Y. 1984). “The statute was meant to empower consumers; to even the playing field in their disputes with better funded and superiorly situated fraudulent businesses. It was not intended to supplant an action to recover damages for breach of contract between parties to an arm’s length contract.” *Teller*, 213 A.D.2d at 148. “The goals of GBL § 349...were major assaults upon fraud against consumers, particularly the disadvantaged.” *Id.* “The consumer-oriented nature of the statute is evidenced by the remedies it provides. Section 349(h) provides parties with the opportunity to receive the greater of actual damages or \$50.” *Genesco*, 593 F. Supp. 2d at 751.

To state a prima facie case under § 349, Plaintiff must show: “first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act.” *Stutman v. Chemical Bank*, 95 N.Y.2d 24, 29 (N.Y. 2000). With regard to the first factor, “the gravamen of the complaint must be consumer injury or harm to the public interest.” *Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 264 (2d Cir. 1995). “The critical question, then, is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer or a competitor.” *Id.*

Consumer-Oriented Conduct

In this case, there is no question that, to the extent Plaintiff suffered a redeemable loss on account of Defendant’s behavior, it is not of the type that § 349 seeks to remedy. To show consumer-oriented conduct, Plaintiff would have to “demonstrate that the acts or practices [complained of] have a broader impact on consumers at large. *Private contract disputes, unique to the parties...*would not fall within the ambit of the statute.” *Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 25 (N.Y. 1995) (emphasis added).

The Complaint focuses almost entirely on the losses suffered by Plaintiff and his business, rather than to consumers or Plaintiff’s patients. Specifically, Plaintiff complains of “loss of all patients who suffered damages,” “damage to professional reputation,” “loss of income from former patients...patient referrals...loss of professional time,” “substantial additional marketing, training and advertising costs,” “immeasurable and irreversible harm to his professional reputation...as well as substantial economic harm to his professional medical

practice.” (Complaint ¶¶ 9, 18, 32.) Under these circumstances, Plaintiff’s claim must fail; “[w]here the gravamen of the complaint is harm to a business as opposed to the public at large, the business does not have a cognizable cause of action under § 349.” *Gucci Amer., Inc. v. Duty Free, Ltd.*, 277 F. Supp. 2d 269, 274 (S.D.N.Y. 2003) (trademark infringement plaintiff could not bring § 349 action because “core harm” is to another business and not consumers, despite consumers’ purchase of counterfeit goods); *see also In re Rezulin Prods. Liability Litigation*, 392 F. Supp. 2d 597, 613 (S.D.N.Y. 2005) (health benefit providers could not recover under § 349 where defendant allegedly misrepresented safety of a drug intended to treat diabetes because “the nature of this marketing effort – communication from one sophisticated business to another – was quite different from that of any promotion aimed directly at diabetes patients”); *Pfizer, Inc. v. Stryker Corp.*, 2003 WL 21660339, at *4 (S.D.N.Y. Jul. 15, 2003) (“Although consumers eventually stood to be affected by any defects in the product at issue, the questions whether [seller] told [buyer] the truth when it represented that the business was in compliance with law and whether it intended to comply with its notice and related obligations are essentially private matters.”); *New York Univ. v. Continental Ins. Co.*, 87 N.Y.2d 308 (N.Y. 1995) (allegations of sham investigation by insurance company not consumer oriented because of, *inter alia*, sophistication of the parties, uniqueness of the agreement and absence of disparate bargaining positions).¹

¹ The line of New York state and federal cases cited by Plaintiff in support of its argument that a physician may bring an action under GBL § 349 are inapposite, as those cases, insofar as they discuss § 349, deal only with the issue of standing, and not the public interest. *See, e.g., Vitolo v. Dow Corning Corp.*, 166 Misc.2d 717, 724 (N.Y. Sup. Ct. 1995) (addressing issues of standing under § 349 and finding that any person who has been injured due to a violation of § 349 may sue); *see also Blue Cross & Blue Shield of New Jersey v. Phillip Morris USA, Inc.*, 178 F. Supp. 2d 198, 240-1 (E.D.N.Y. 2001) (Weinstein, J.) (*quoting Vitolo v. Dow*

B. *Fraud and Fraudulent Inducement*

“Under New York law, a fraud cause of action generally does not arise where the alleged fraud merely relates to a breach of contract.” *EED Holdings v. Palmer Johnson Acquisition Corp.*, 387 F. Supp. 2d 265, 278 (S.D.N.Y. 2004). However, under certain limited circumstances, it is possible to sustain a claim of fraudulent inducement arising out of a contractual relationship. To do so, “one must plead any of the following: (i) a legal duty separate from the duty to perform under the contract; or (ii) a fraudulent misrepresentation collateral or extraneous to the contract; or (iii) special damages that are caused by the misrepresentation and unrecoverable as contract damages.” *G-I Holdings, Inc. v. Baron & Budd*, 179 F. Supp. 2d 233, 269 (S.D.N.Y. 2001). In this instance, Plaintiff alleges both that Defendant owed him a legal duty separate from the duties inherent in the contract and that Defendant made fraudulent misrepresentations upon which Plaintiff relied in entering into the contract.

Duty of Care Independent of Contractual Duties

Plaintiff’s argument that Defendant owed him a legal duty separate and distinct from the contract is based largely on *Sommer v. Federal Signal Corp.*, 79 N.Y.2d 540 (N.Y. 1992). In *Sommer*, the plaintiff alleged that defendant was negligent in turning off plaintiff’s fire alarm system, in violation of both the agreement between the parties and a New York City fire regulation, and thereby exacerbated a fire which damages plaintiff’s 43-story building. *Id.* at 552. As a result, the court found that plaintiff’s claims sounded in both tort and contract. *Id.* at

Corning for the proposition that some states permit suit by physicians, noting the lack of a clear rule across jurisdictions, and acknowledging usual requirement of either public interest or consumer nexus).

553 (“Fire alarm companies thus perform a service affected with a significant public interest; failure to perform the service carefully and competently can have catastrophic consequences. The nature of [defendant’s] service and its relationship with its customer therefore gives rise to a duty of reasonable care that is independent of [defendant’s] contractual obligations.”).

The Court of Appeals clarified *Sommer* in *New York Univ. v. Continental Ins. Co.*, 87 N.Y. 308 (N.Y. 1995) (“*NYU*”), in which plaintiff argued that New York Insurance Law imposed an additional duty on defendant to exercise due care in investigating claims and dealing fairly with their insured and the public at large. *Id.* at 317. There, the Court of Appeals stated that it “did not [in *Sommer*]...suggest that statutory provisions necessarily or generally impose tort duties independent of contract obligations.” *Id.* The court recognized the “catastrophic consequences” that could flow from the type of negligence found in *Sommer* and the special importance of the careful performance of fire alarm services contracts. *Id.* Upon these bases, the court declined to find a separate duty in *NYU* and rejected plaintiff’s argument that Insurance Law created a separate duty of care. *See also Pfizer, Inc. v. Stryker Corp.*, 2003 WL 21660339, at *2 (S.D.N.Y. Jul. 15, 2003) (describing *Sommer* and its progeny as a “limited class of cases in which a strong public interest in the careful performance of particular contractual obligations may give rise to a tort duty of due care” and finding public interest in defendant’s performance of several covenants found in contract supplying prosthetic devices not “so exceptional as to warrant the creation of an independent extra-contractual duty”). These cases suggest that imposition of an independent duty of care in an arms-length business transaction is reserved for the most serious of situations directly affecting the public at large, and not sophisticated parties.

Additionally, the *NYU* decision held that “if the statute does not permit a private right of

action...it cannot be construed to impose a tort duty of care...separate and apart from the...contract.” 87 N.Y.2d at 318. In this case, Plaintiff argues that regulations promulgated by the FDA, 21 C.F.R. part 820, impose a separate duty on Defendant to perform the contract with due care, as Defendant is required by law to, *inter alia*, investigate complaints with its products and disclose known risks to those responsible for assuring the quality of the product. (Pl. Mem. of Law Ex. 8.) However, like the state insurance law regulation in *NYU*, there is no private right of action to enforce FDA regulations, *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997), making Plaintiff’s argument unpersuasive.

Fraudulent Misrepresentations Collateral or Extraneous to the Contract

“Where...a party warrants and represents a present existing fact, there simply is no reason why it should not have a remedy in contract for breach of the warranty and a remedy in tort for deliberate, fraudulent misrepresentation, assuming the facts otherwise justify such relief.” *See Pfizer*, 2003 WL 21660339, at *1; *see also EED Holdings v. Palmer Johnson Acquisition Corp.*, 387 F. Supp. 2d 265 (S.D.N.Y. 2004) (“alleged misrepresentations of fact made to induce the contract are collateral to the actual terms of the contract”). However, on these facts, Plaintiff is unable to show a fraudulent misrepresentation that encouraged him to enter the contract.

“To recover damages for fraud, a plaintiff must prove (1) a misrepresentation or omission of material fact which was false and known to be false by the defendant, (2) the misrepresentation was made for the purpose of inducing plaintiff to rely upon it, (3) justifiable reliance of the plaintiff on the misrepresentation or material omission, and (4) injury.” *Jablonski v. Rapalje*, 14 A.D.3d 484, 487 (N.Y. App. Div. 2005). At a minimum, Plaintiff has failed to

demonstrate his justifiable reliance on any misrepresentation made by Defendant. Though Plaintiff argues that, under *Jablonski*, “whether reliance upon the fraudulent misrepresentation is justified is a question of fact,” Pl. Mem. of Law at 13, the full *Jablonski* quote reads: “whether a party could have ascertained the facts with reasonable diligence so as to *negate justifiable reliance* is a factual question.” *Jablonski*, 14 A.D.3d at 488 (emphasis added). Therefore, this sentence stands for the proposition that *once demonstrated* by Plaintiff, justifiable reliance can be rebutted by Defendant by a preponderance of the evidence under certain circumstances. The statement does not assist Plaintiff in making a prima facie showing that he in fact relied on any misrepresentations in deciding to enter into the agreement with Defendant. *See generally Vermeer Owners, Inc. v. Gerald Guterman*, 78 N.Y.2d 1114, 1116 (N.Y. 1991) (“Although it is clear that the offering plan contained statements that were demonstrably false...[n]othing in this record establishes that plaintiffs in fact relied on any misrepresentation by defendants to their detriment.”); *see also Pacs Indus. v. Cutler-Hammer, Inc.*, 103 F. Supp. 2d 570 (E.D.N.Y. 2000) (Spatt, J.) (granting judgment on the pleadings dismissing fraud claim where only reliance shown was purchase of defendant’s product).

Though Plaintiff now claims that “Mentor’s representations with respect to the one to two percent deflation rate were ‘critical’ to his decision to switch to the MLV,” Pl. Mem. of Law at 14, he made no such suggestion prior to his opposition papers to Defendant’s motion for summary judgment. These new allegations are insufficient to create a genuine issue of material fact because: “[i]t is well settled in this circuit that a party’s affidavit which contradicts his own prior deposition testimony should be disregarded on a motion for summary judgment.” *Mack v. United States*, 814 F.2d 120, 124 (2d Cir. 1987); *see also Hayes v. New York City Dep’t of*

Corrections, 84 F.3d 614, 619 (2d Cir. 1996) (“[F]actual issues created solely by an affidavit crafted to oppose a summary judgment motion are not ‘genuine’ issues for trial.”); *Perma Research & Development Co. v. Singer Co.*, 410 F.2d 572, 578 (2d Cir. 1969) (“If a party who has been examined at length on deposition could raise an issue of fact simply by submitting an affidavit contradicting his own prior testimony, this would generally diminish the utility of summary judgment as a procedure for screening out sham issues of fact.”).

The fact that Plaintiff may have inquired as to the deflation rate does not show his reliance thereon, particularly because Plaintiff admitted in his deposition that he did not remember the exact deflation rate that he was told by Defendant. (Def. Mem. of Law Ex A at 284.) At oral argument, Plaintiff repeatedly directed the Court’s attention to documents that, it argues, prove Defendant’s material misrepresentation as to the deflation rate of the MLVs and/or Plaintiff’s knowledge of these alleged misrepresentations – but not reliance thereon. (*See, e.g.*, Transcript of 3/17/06 Oral Argument at 23 (pointing to Defendant’s 1991 “Dear Doctor” letter alleging deflation rate of less than 2%); *id.* at 25 (suggesting that “a reasonable surgeon has a right to rely” on deflation rates); *id.* at 26-28 (in response to Court’s request that Plaintiff demonstrate a prima facie showing of reliance, Plaintiff directs Court to a document regarding Defendant’s knowledge of the umbilicus technique rather than Plaintiff’s reliance on deflation rate); *id.* at 31 (equating Plaintiff’s deposition testimony that he thinks he was told that the deflation rate was 1-2% with Plaintiff’s reliance thereon).) At no point did Plaintiff present evidence prior to the instant motion for summary judgment that he did, in fact, rely on any of the statements or documents to which he draws this Court’s attention. Therefore, having failed to demonstrate each element of his fraud claim by clear and convincing evidence (as is required at

this stage, *Dallas Aerospace, Inc. v. CIS Air Corp.*, 352 F.3d 775, 784 (2d Cir. 2003)), Plaintiff claims of fraud and fraudulent inducement must fail.

CONCLUSION

The Complaint is hereby dismissed. Section 349 of New York's General Business Law was not intended to apply to arms-length business transactions between sophisticated parties, but rather, ought to redress wrongs committed against consumers in general. According to the Complaint, the wrongs committed by Defendant and damages sought are almost entirely related to Plaintiff's business and reputation. Section 349 does not apply under these circumstances. Additionally, Plaintiff's claim that Defendant's fraudulent misrepresentations induced him to enter into an agreement to purchase the MLV implants is without merit, as Plaintiff has failed to show his reliance on any misrepresentation prior to contracting with Defendant to purchase the implants. That claim, too, is dismissed. The Clerk of the Court is directed to close the case.

SO ORDERED.

Dated: March 31, 2006
Brooklyn, NY

S/
SANDRA L. TOWNES
UNITED STATES DISTRICT JUDGE